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April 28, 2015

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

Generic Name: Functionalized pyridine

This letter is to inform you of the results of an acute inhalation toxicity study with the above referenced test substance. The test substance is an R&D substance and to the best of our knowledge not on the public inventory.

Ten healthy Sprague-Dawley derived, albino rats (5/sex) were exposed to the test atmosphere for 4 hours via nose only exposure. Chamber concentration and particle size distributions of the test substance were determined periodically during the exposure period. The animals were observed for mortality, signs of gross toxicity, and behavioral changes at least once daily for 14 days following exposure. Body weights were recorded prior to exposure and again on Days 1, 3, 7 and 14 (termination), where Day 1 is one day post-exposure. Necropsies were performed on all animals at terminal sacrifice. The gravimetric chamber concentration was 5.30 ± 0.51 mg/L (mean \pm SD).

All animals survived. Following exposure, all animals were hypoactive, exhibited irregular respiration, tremors, and/or ocular discharge. However, all animals recovered from these symptoms by Day 3.

Sincerely,

Substantiating Claims of Confidentiality in Submissions to the TSCA §8(e) Office

Confidential Business Information Substantiation

1.	Is your company asserting this confidential business information (CBI) claim on its				
	own	behalf? If the answer is no, please provide company name, address and	telephone		
number of entity asserting claim.					

[]

2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

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3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

[

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4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

[

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5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

[

6.		Does the information claimed as confidential appear or is it referred to in any of the following:			
	a.	Advertising or promotional material for the chemical substance or the resulting and product;[
	b.	Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale); []			
	c.	Professional or trade publications; or []			
	d.	Any other media or publications available to the public or to your competitors.			
		answered yes to any of the above, indicate where the information appears, include, and explain why it should nonetheless be treated as confidential.			
7.	regard	Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.			
	[]				
	Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertis sual processes and your competitor's access to your customers. Address each piece of nation claimed CBI separately.				
	[
9.		e substance been patented in the U.S. or elsewhere? Is a patent for the substance tly pending?			
	[

10.	Is this substance/product commercially available and if so, for how long has it been available on the commercial market? []		
	a.	If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?	
]	
	b.	If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.	
	c.	What is the substance used for and what type of product(s) does it appear in.	
].	
11.	Describe whether a competitor could employ reverse engineering to identically recreate the substance?		
	[
].	
12.	Do you assert that disclosure of this information you are claiming CBI would reveal:		
	a.	confidential processes used in manufacturing the substance; []	
	b.	if a mixture, the actual portions of the substance in the mixture; []	
	c.	information unrelated to the effects of the substance on human health or the environment? []	
reveale	-	r answer to any of the above questions is yes, explain how such information would be	
13. a CAS	Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for S number, include a copy of the contract with CAS.		
	[]	
14.		substance or any information claimed CBI the subject of FIFRA regulation or ing? If so, explain.	
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